

**REMARKS**

Claims 1, 2, 4-8, 10-17, 19-20, 22-23 and 56-73 are pending in the application and are currently rejected. No claims have been amended. Claims 15 and 73 are allowed. Claim 23 is objected to. Applicants note that, though claim 21 is listed among the rejected claims, claim 21 has been cancelled. In light of the remarks herein, reconsideration of claims 1, 2, 4-8, 10-17, 19-20, 22-23 and 56-73 is respectfully requested.

**Amendments to the Claims**

The Applicant's gratefully acknowledge the Examiner's determination that claims 15 and 73 are allowed and that claim 23 is allowable if rewritten in independent form. Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants. Therefore, the Applicants have not amended the claims.

**Claim Rejections under 35 U.S.C. § 103**

*Claims 1, 2, 4-8, 10-14, 19-20 and 56-72*

Claims 1, 2, 4-14, 19-21 and 56-72 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of U.S. Patent No. 6,273,884 to Altshuler et al. (herein "Altshuler"). The claims, however, are patentable because there is no motivation to modify the psoriasis treatment device of Lerner with the total internal reflection lens of Altshuler.

Claim 1 is directed to an apparatus for treating the skin, comprising an applicator having at least one protuberance comprising a skin-contacting surface, and at least one optical radiation source. The apparatus also includes a total internal reflection mechanism *to prevent a portion of the radiation from passing through said skin-contacting surface unless in contact with the skin.*

Lerner, the primary reference, is directed to a fiber optic psoriasis treatment device for applying UV radiation. Lerner does not disclose or suggest a total internal reflection mechanism that prevents a portion of the radiation from passing through said skin-contacting surface, unless

in contact with the skin. Rather, Lerner teaches away from such a mechanism by relying on an opposite principle of operation. Lerner instead provides features and discloses a procedure in which UV radiation is transmitted even when not in contact with the skin. As shown in FIGS. 1, 2, 3A, and 3B, the distal tips of the fibers fixed to the body member of the apparatus have either UV radiation transmitting spherical elements or rounded ends, both of which have “a radius of curvature of about 0.25-2.0 mm, to ensure that minimal damage is done to the skin during use.” (see Lerner, column 4, lines 25-31). Lerner, therefore, teaches a device that is *configured to facilitate UV radiation transmission even when not in contact with the skin* to achieve a purpose other than energy conservation and safety measures as taught by the Applicants. Furthermore, Lerner discloses a procedure for controlling the dose of radiation that requires UV radiation to pass even when the ends are not in contact with the skin. Specifically, Lerner’s device “might require the user to *point the output onto a detector* which measured irradiance appropriately” (see id. at column 5, lines 65-68).

As discussed in the Manual of Patent Examining Procedure §2143.02 Section VI, “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie obvious*.” Adding the total internal reflection mechanism recited in amended claim 1 would change of the principle of operation of the tip ends of the fibers of the Lerner device and the suggested manner of calibrating the device. Accordingly, Lerner cannot be combined with Altshuler to render amended claim 1 obvious.

Claims 2, 4-8, 11-14, 19-20, and 56-60 all depend from claim 1, and are thus patentable over the cited art for at least the same reasons that claim 1 is patentable. In addition, the claims are patentable for other reasons.

In claims 6-7, the Applicants claim a range of power densities that extend significantly higher, by several orders of magnitude, than those disclosed by Lerner. Further, Applicants’ disclose using a broader range of energy, that is not limited to UV radiation as in Lerner. As the examiner notes, Lerner discloses power densities that are preferably 1-10 mW/cm<sup>2</sup> for UV-B radiation and 30- 1000 mW/cm<sup>2</sup> for UV-A radiation. In contrast, the Applicants, in Claim 6,

claim a range of “between approximately 1 mW/cm<sup>2</sup> and approximately 100 W/cm<sup>2</sup>, the radiation depending at least on the condition being treated and the wavelength of the radiation.” Similarly, claim 7 recites a range of power densities of “between 10 mW/cm<sup>2</sup> and 10 W/cm<sup>2</sup>. ”

Claim 10 is directed to a skin treatment apparatus that includes “a skin contacting end of each protuberance [having] total internal reflection for [] radiation when not in contact with the skin, but passes radiation to the skin when in contact therewith.” Accordingly, claim 10 is not obvious in light of Lerner and Altshuler since Lerner teaches away from utilizing distal fiber ends to confine radiation when not in contact with the skin, as discussed above.

Regarding claims 59 and 60, Lerner does not teach or suggest the arrays of optical sources as claimed by Applicants, and there is no motivation to combine those claimed features with Lerner. Lerner discloses and claims embodiments having only a single UV source. (See e.g. Cols. 4:5-10; 4:63-5:6 and claims 1 and 3-8.) Further, Lerner discloses embodiments using single fluorescent bulbs, lamps (such as tungsten halogen lamps or mercury lamps), or an excise laser. (See Lerner Cols. 2:40-49; 4:5-10; 4:63-5:6.) Lerner does not teach or suggest an array of optical sources, including an array of diode sources or an array of other types of sources, and there is no evident motivation to combine the references.

Claim 61 is directed to a skin treatment apparatus that includes a total internal reflection mechanism coupled to said skin-contacting surface to prevent at least a portion of the radiation from passing through said skin-contacting surface unless in contact with a surface having an index of refraction approximately greater than or equal to the index of refraction of the skin contacting surface. As such, claim 61 is not obvious in light of Lerner and Altshuler for substantially the same reasons that claim 1 is not obvious. Accordingly, claims 62-67, dependent from claim 61, are also not obvious.

Claim 68 is directed to a skin treatment apparatus having an optical radiation source that delivers optical radiation such that at least a portion of the radiation passes to the skin only when the surface contacts the skin. Accordingly, claim 68 also is not obvious in light of Lerner and

Altshuler for substantially the same reasons that claim 1 is not obvious. Accordingly, claims 69-72, dependent from claim 61, are also not obvious.

*Claim 16*

Claim 16 is rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of Altshuler and further in view of U.S. Patent No. 6,572,637 to Yamazaki et al. (herein “Yamazaki”). Claim 16, dependent from claim 1, is patentable for essentially the same reasons that claim 1 is patentable. In particular, like Lerner and Altshuler, Yamazaki fails to provide the necessary motivation to combine the references to include a total internal reflection mechanism. Yamazaki is silent in that regard.

*Claim 17*

Claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Lerner in view of Altshuler and further in view of U.S. Patent No. 5,445,608 to Chen et al. (herein “Chen”). Claim 17, dependent from claim 1, is patentable for essentially the same reasons that claim 1 is patentable. In particular, like Lerner and Altshuler, Chen fails to provide the necessary motivation to combine the references to include a total internal reflection mechanism.

Further, the references effectively teach away from their combination. The procedures and devices disclosed in Chen are substantially different in kind from those disclosed in Lerner. Lerner concerns a surface skin treatment brush for inflammatory dermatoses, while Chen concerns an invasive in vivo procedure using a catheter, in which a photoreactive agent is administered through the catheter to inject it into the treatment site. (Compare Lerner Col. 2:34-39 and Chen Col. 4:7-15.) Further, Lerner teaches a procedure in which a “medicant or lubricant” is preferably applied to a surface region to be treated during a “pre-treatment” step, (see Lerner Col. 3 10-25), while Chen discloses injecting the “photoreactive agent” to perfuse the treatment site in vivo after the catheter in Chen device has been inserted into the tissue, (see Chen Col. 4:7-15). There is no evident motivation to include the fluid delivery system of a catheter system with Lerner’s device for treating tissue at the surface. The two devices are so different that it would not be obvious to combine them.

Claims 1, 2, 4-5, 8, 10-14, 19-20, 22 and 56-72 stand rejected under 35 U.S.C. §103(a) as being unpatentable over German Patent G 91 02 407.2 to Mink (“Mink”) in view of U.S. Patent 6,273,884 to Altshuler et al. (“Altshuler”). All of the rejected claims, however, are patentable, because it is not obvious to combine the device in Mink with a total internal reflection mechanism as taught in Altshuler.

Each of the rejected independent claims share a similar characteristic, i.e., at least a portion of the radiation does not pass unless the apparatus is in contact with a surface such as, for example, skin. The rejected independent claims are summarized as follows.

- Independent claim 1 is directed to an apparatus for treating the skin, comprising an applicator having at least one protuberance comprising a skin-contacting surface, and at least one optical radiation source. The apparatus also includes a total internal reflection mechanism *to prevent a portion of the radiation from passing through said skin-contacting surface unless in contact with the skin.*
- Independent claim 10 is directed to an apparatus for treating the skin, wherein “a skin contacting end of each protuberance has total internal reflection for the radiation when not in contact with the skin, but *passes radiation to the skin when in contact therewith.*”
- Independent claim 61 is directed to an applicator having at least one protuberance comprising a skin-contacting surface. The applicator includes “a total internal reflection mechanism coupled to said skin-contacting surface to prevent at least a portion of the radiation from passing through said skin-contacting surface *unless in contact with a surface* having an index of refraction approximately greater than or equal to the index of refraction of the skin contacting surface.”
- Independent claim 68 is directed to an apparatus for treating skin using an optical radiation source, “wherein at least a portion of the radiation passes to the skin *only when the surface contacts the skin.*”

As the examiner notes, Mink does not teach total internal reflection, and there is no indication of any motive or reason to combine Mink with Altshuler. Generally, Altshuler teaches a different type of device having a total internal reflection mechanism that is different than that disclosed in the present application. For example, Mink appears to show in figures 2 and 3 bristles having hollow cylindrical channels used to conduct light from an array of light sources, and the Applicants are unable to discern any stated rational or benefit from restraining radiation when the device is not in contact with the tissue to be treated. Thus, it appears that Mink’s

hairbrush has a fundamentally different principle of operation from the devices of Altshuler. While Altshuler discloses, for example, embodiments that include solid lenses through which the radiation passes, Mink does not appear to disclose such a mechanism of operation. Instead, the light in Mink appears to pass through empty space. Thus, there would be no obvious motivation or mechanism to provide a device having total internal reflection as claimed in the present application.

Without modifying the fundamental operation of Mink, there would be no motivation to apply the teachings of Altshuler. As discussed in the Manual of Patent Examining Procedure §2143.02 Section VI, “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” Adding the total internal reflection mechanism recited in claims 1, 10, 61 and 68 would change of the principle of operation of the hairbrush disclosed in Mink. Accordingly, Mink cannot be combined with Altshuler to render amended claim 1 obvious.

For the reasons discussed above, it would also not be obvious to combine either Yamazaki or Chen with Mink and Altshuler.

Finally, there is not a sufficient evidentiary basis in the present record for concluding with respect to either Lerner or Mink that “[i]t would have been obvious to one skilled in the art to use total internal reflection as taught by Altshuler et al. in the invention[s]” of Mink and Lerner. (See office action at 5 (concerning Mink) and similar statement at page 3 (concerning Lerner)). The only analysis provided in the present office action in support of the conclusion that it would be obvious to so combine Altshuler with Mink and Lerner are the two nearly identical conclusory statements cited above. These statements conclude only that it would have been obvious to combine the references, but do not provide the required explanation or evidentiary basis for that conclusion. The recent guidelines issued by the United State Patent and Trademark Office on October 10, 2007 dealing with obviousness rejections after *KSR v. Teleflex* emphasize that such conclusory statements are insufficient to support an obviousness rejection. (See Notice, 72 Fed. Reg. 57526 (Oct. 10, 2007). In the notice, the USPTO acknowledged the

Supreme Court's holding that conclusory statements regarding obviousness were insufficient. The USPTO further noted that the analysis supporting a rejection under 35 U.S.C. 103 "should be made explicit." There is no explicit analysis supporting the obviousness rejections in the present office action as required.

Given the differences in structure, function and purpose between Mink, Lerner and Altshuler, Yamazaki, and Chen as well as the differences between each of those references and the inventions disclosed by the Applicants, it would not be obvious under any of the rationales provided by the USPTO in its Notice of October 10, 2007 to combine and of Altshuler, Chen or Yamazaki with Mink or Lerner to attain the claimed inventions. Further, because there is no explicit support under any rationale for rejecting the present claims as obvious, Applicants request that the Examiner withdraw the present rejection of the claims.

Claims 2, 4-8, 11-14, 16-17, 19-20, 22, 23, 56-60, 62-67, and 69-72 all depend from one of claims 1, 10, 61 and 68, and are thus patentable over the cited art for at least the same reasons that claims 1, 10, 61 and 68 are patentable. Accordingly, Claims 1-2, 4-8, 10-14, 16-17, 19-20, 22, 23 and 56-72 are novel and patentable over Lerner or Mink in combination with Altshuler and the other cited references.

## CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the Examiner deems that the amendments and remarks do not overcome the stated grounds for rejection, the Applicants kindly request that the Examiner telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

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